



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEE

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

DATE OUT: June / 03 / 2015

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: DP424355 **EPA Reg. No.:** 82542-3
PRODUCT NAME: Paraquat Concentrate
COMPANY: Source Dynamics, LLC
FOOD USE [Yes] INTEGRATED FORMULATION [X]
PCC: 061601 **Decision No.** 497129
ACTION CODE: R351 **Pesticidal use:** Herbicide

FROM: Hari Mukhoty, DVM, PhD
Product Chemistry Team
Technical Review Branch / RD (7505P)

Handwritten signature and date: 6/9/15

TO: Sarah Meadows, RMR / Mindy Ondish, RM 25
Herbicide Branch / RD (7505P)

INTRODUCTION:

The Registrant has submitted an amended basic CSF (dated: 10/29/2014) as alternate formulation (Alt. # 4) to the aforesaid basic for registration under EPA Reg. No. 82542-3. The product chemistry data have been submitted under MRIDs: 495078-01 & -02 and data matrix dated 10/29/2014.

The aforesaid alternate MUP is manufactured by [REDACTED]

Chemical Analyses were performed by BIOAGRI Laboratories Ltd. in Brazil.

Label text previously accepted indicates that this proposed MUP is intended to be formulated into end-use products with food uses & other terrestrial non-food crops approved by EPA.

CITAB has been requested to evaluate the product chemistry data required for the registration of the proposed alternate MUP.

SUMMARY OF FINDINGS:

1. The proposed TGA/MUP contains the active ingredient: Paraquat dichloride (43.2%).
2. The overall mean of the active ingredient from the five batch analysis is 44.46% [MRID: 495078-02, Page 8 of 106]. This is the overall mean of the purity of the active ingredient produced through the use of starting materials at the end of the production process.

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3. The proposed nominal concentration of the active ingredient in the MUP is 43.2%. The nominal concentration of the active ingredient (43.2%) in alternate MUP matches with the label claim (43.2%).

The certified limits of the active ingredient and impurities are standard [Proposed CSF dated 10/29/2014]. The impurity profile of the proposed alt # 4 formulation is different from that of the accepted basic formulation (Dated: 01/28/2010).

4. This CSF has been reviewed by I.I.A. group and they have concluded that it contains inert ingredients approved for food uses (Pre- and Post-Harvest Applications).

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively for the proposed formulation [MRIDs: 495078-01 & -02].

6. The active ingredient were quantified and characterized by HPLC method using DAD detector. The content of [REDACTED] and [REDACTED] was determined by HPLC-DAD. The identity of the technical sample was also confirmed by mass spectrometer (MS) and DAD detectors. Total [REDACTED] were determined by GCMS method. The water content was determined by Karl Fischer Titration [MRID: 495078-02].

The method to determine active ingredient for precision, linearity and accuracy was validated [MRID: 495078-02].

Similar analytical techniques can also be applied for Enforcement Analytical Method.

7. Toxicity of relevant impurities are described in page of this review.

CONCLUSIONS:

1. CITAB has reviewed the CSF (dated: 10/29/2014) for the proposed alternate TGA/MUP and has found it to be acceptable.

2. Product chemistry Group A data are satisfied and acceptable. Group B data are not required for the proposed alternate formulation.

Inert ingredient information may be entitled to confidential treatment

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PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 10/29/2014)	A	495078-01 & -02
830.1600. Beginning Materials	A	"
830.1620. Production process	A	"
830.1650. Formulation process	A	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis #	A	495078-02
830.1750. Certified Limits	A	CLs are standard.
830.1800. Enforcement Analytical Method #	A	495078 -02

A = Acceptable NA = Not Applicable G = data gap

Analytical Methods: The active ingredient was quantified and characterized by HPLC method using DAD detector. The content of [REDACTED] (intentionally added) and [REDACTED] was determined by HPLC-DAD. The identity of the technical sample was also confirmed by mass spectrometer (MS) and DAD detectors. Total [REDACTED] were determined by GCMS method. The water content was determined by Karl Fischer Titration [MRID: 495078-02].

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CONFIDENTIAL APPENDIX

Product Identity of Paraquat Concentrate EPA Reg. No. 82543-3

PRODUCT IDENTITY *MRID: 495078-01*

Common Name: paraquat dichloride

Chemical Name: 1,1'-dimethyl-4,4'-bipyridinium dichloride [CA]

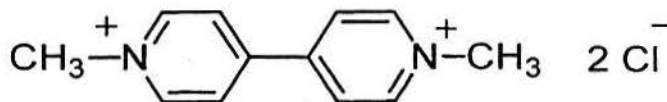
1,1'-dimethyl-4,4'-bipyridilium dichloride [IUPAC]

CAS RN: 1910-42-5

Molecular Weight: 257.2

Molecular Formula: $C_{12}H_{14}Cl_2N_2$

Structure:



Melting Point: decomposes at $\sim 340^\circ\text{C}$

Vapor Pressure: <0.01 mPa at 25°C

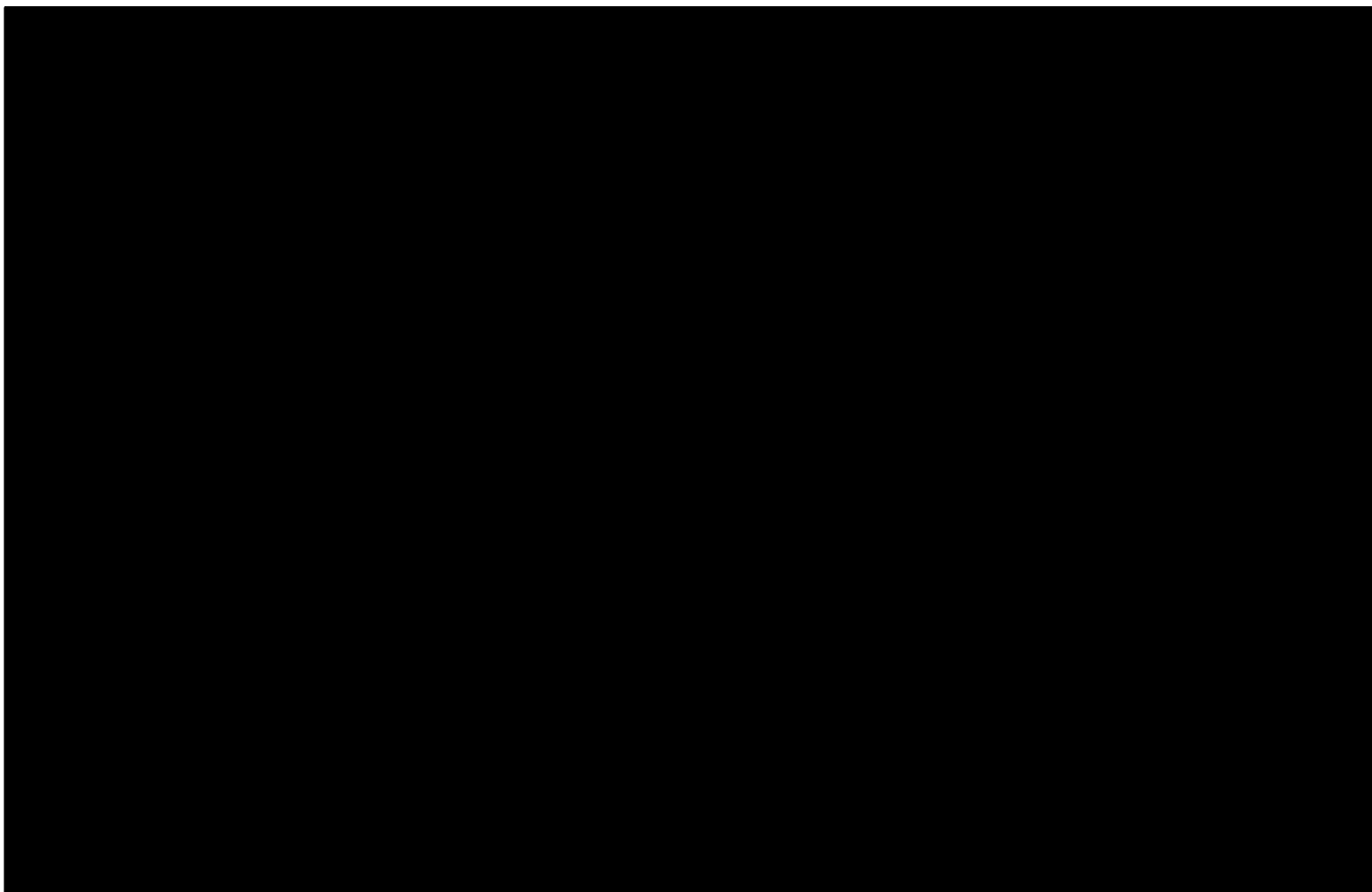
K_{ow} : $\log P = -4.5$ at 20°C

Solubility in Water: ~ 620 g/L at 20°C

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CONFIDENTIAL APPENDIX

Results of five batch analysis for EPA Reg. No.: 82542-3 (Active & Impurity profile)

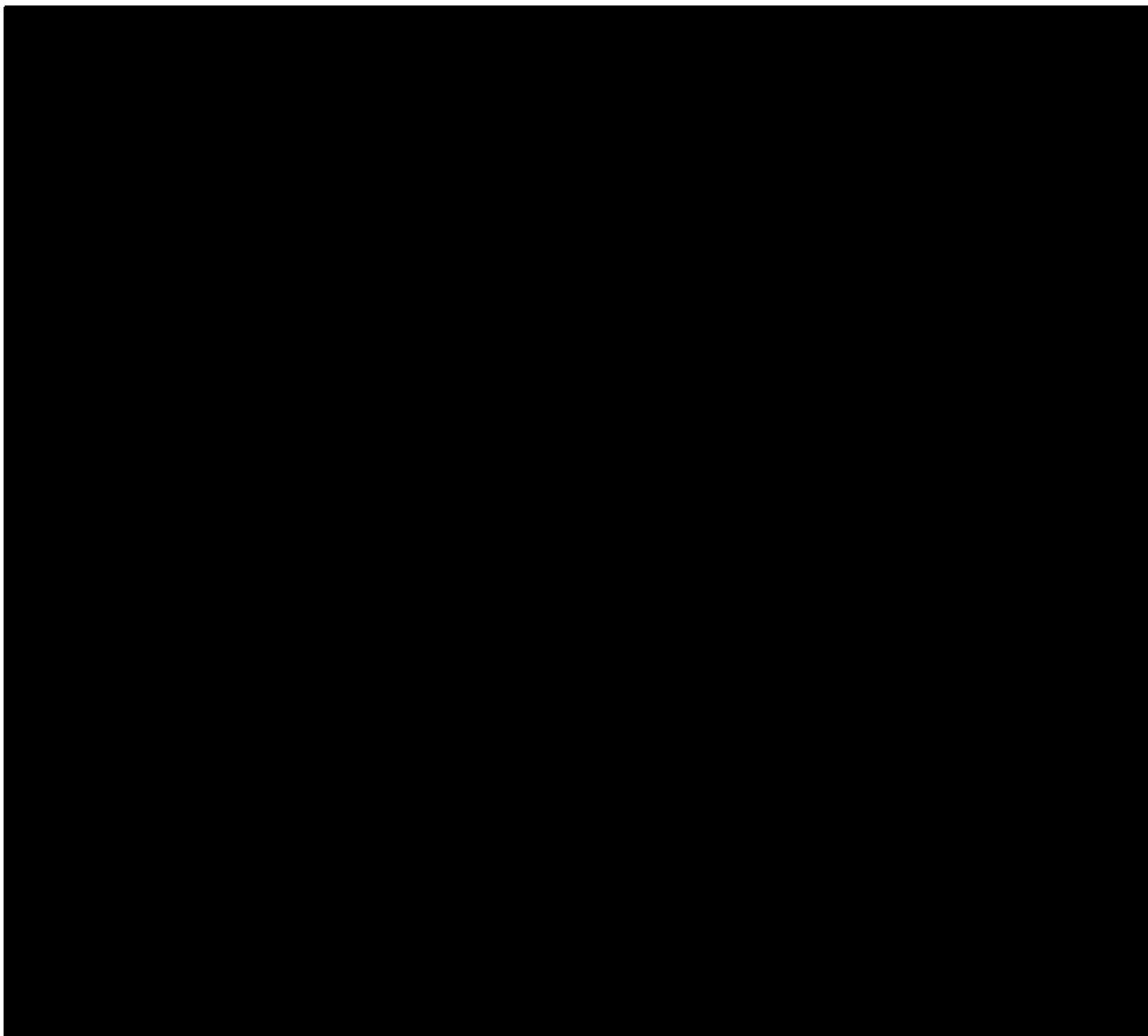


Manufacturing process information may be entitled to confidential treatment

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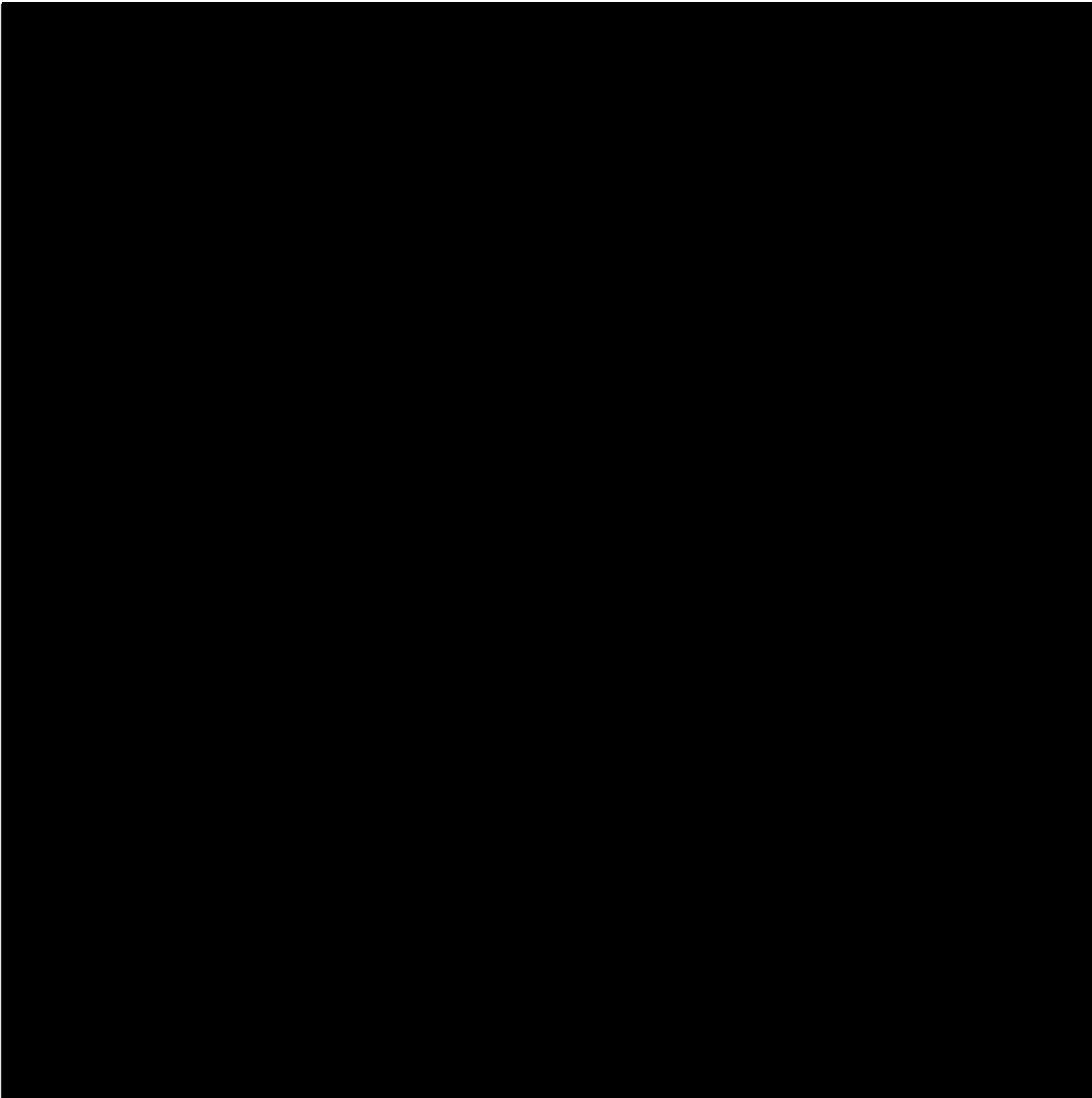
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